

### REMARKS

The Office Action dated September 7, 2001 has been carefully reviewed and the foregoing amendments to the application have been made in consequence thereof. Claim 18 has been cancelled. Claims 1, 5, 7, 9, 12, 14, and 16 have been amended in order to advance the prosecution of this application. Claims 1- 16 remain active in this application.

The Examiner rejected claims 7, 8, 12, and 13 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Claims 7 and 12, on which claims 8 and 13 depend, respectively, have been amended to particularly point out and to include the step of forcing the concentrated solution through a spinneret for producing insoluble fibers of polypeptides as recommended by the Examiner.

The amended claims are supported by the Examples which are described in the specification.

Therefore, in view of the amendments described above, Applicants assert that claims 7, 8, 12, and 13 particularly point out and distinctly claim the invention.

The Examiner rejected claims 1, 3-9, 11-14, 16, and 18 under 35 U.S.C. 102(b) as being anticipated by Lombardi et al.

Claims 1, 9 and 14 have been amended to describe the recovered solution as comprising one or more purified polypeptides. Thus, the claimed method is patentably distinguishable over Lombardi et al.

The Examiner rejected claims 1-16 and 18 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Claim 18 has been canceled. Claim 1 has been amended to identify the recovered solution of line 8 in the claim and its relationship to the solution of line 5 in the claim. Claim 5 has been amended to teach that the acid is an organic acid. Claim 6 is dependent on claim 5.

Claims 9 and 14 have been amended to more clearly describe that the insoluble material is in the mixture of step b, and that what is encompassed by the term "treating" at the end of the claim is placed in step b wherein it occurs, as indicated by the Examiner. Claims 10-13 and 15 and 16 depend from amended claims 9 and 14.

In view of the amendments described above, Applicants assert that claims 1-16 do particularly point out and distinctly claim the invention.

The Examiner rejected claims 7, 12 and 16 under 35 U.S.C. 112, first paragraph. Claims 7, 12, and 16 have been amended to teach the forcing of concentrated purified solution through a spinneret under conditions wherein insoluble fibers of polypeptides are produced. Thus, the specification is enabling for claims 1, 9, and 14 as further described by claim 7, 12, and 16, as suggested by the Examiner.

In view of the foregoing amendments and remarks, it is believed that claims 1-16 in this application are allowable, and a Notice to that effect is respectfully solicited.

Should the Examiner wish to contact the Applicants' attorney regarding this application, the Examiner is respectfully invited to do so by calling or writing the

undersigned in the Office of Counsel, U.S. Army Soldier and Biological Chemical  
Command, Natick, MA 01760-5035 at 508-233-4510.

Respectfully submitted,

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1. (Twice Amended) A method, comprising:
  - a. providing: i) a biological sample comprising one or more structural polypeptides; and ii) an acid consisting essentially of an organic acid;
  - b. treating said sample with said acid under conditions such that said one or more purified polypeptides is recovered in a solution, said treating comprising mixing said sample with said acid, incubating said mixed sample and acid, and clarifying said mixed sample and acid to yield [a] the recovered solution comprising said one or more purified polypeptides.
5. (Amended) The method of claim 1, wherein said [comprises] is an organic acid.
7. (Twice Amended) The method of claim 1, further comprising the steps of [manipulating said solution under conditions such that insoluble fibers are produced, said manipulating comprising] purifying the solution, [and] concentrating the purified solution, and forcing the concentrated solution through a spinneret under conditions wherein insoluble fibers of polypeptides are produced.
9. (Twice Amended) A method, comprising:
  - a. providing: i) host cells expressing one or more recombinant structural polypeptides, and ii) a solution consisting essentially of an organic acid;
  - b. treating said host cells with said solution to create a mixture[;] of soluble and insoluble material,
  - [c. removing insoluble material from said mixture; and
  - d. recovering said one or more recombinant polypeptides in a solution,]

whereby said treating comprises mixing said cells with said acid, incubating

said mixed cells and acid, and clarifying said mixed cells and acid to yield a recovered solution, said recovered solution comprising one or more purified polypeptides; and

c. recovering said one or more recombinant polypeptides in the recovered solution.

12. (Twice Amended) The method of claim 9, [wherein said recovered one or more recombinant polypeptides in said solution are manipulated under conditions such that insoluble fibers are produced, said manipulated] further comprising purifying the solution, [and] concentrating the purified solution, and forcing the concentrated solution through a spinneret under conditions wherein insoluble fibers of polypeptides are produced.

14. (Twice Amended) A method, comprising:

a. providing: i) bacterial cells expressing one or more recombinant structural polypeptides, and ii) a solution consisting essentially of an organic acid selected from formic acid, acetic acid, propionic acid, butyric acid, and valeric acid;

b. treating said bacterial cells with said solution to create a mixture[;] of soluble and insoluble material,

[c. removing insoluble material from said mixture; and

d. recovering said one or more recombinant polypeptides in a solution,] whereby said treating [comprising] comprises mixing said cells with said acid, incubating said mixed cells and acid, and clarifying said mixed cells and acid

to yield a recovered solution[.], said recovered solution comprising one or more purified polypeptides; and

c. recovering said one or more recombinant polypeptides in the recovered solution.

16. (Twice Amended) The method of claim 14, further comprising the [step] steps of [manipulating said recovered one or more recombinant polypeptides under conditions such that insoluble fibers are produced, said manipulating comprising] purifying the solution, concentrating said recovered one or more recombinant polypeptides to create a concentrated purified solution[;] , and forcing said concentrated solution through a spinneret under conditions wherein insoluble fibers of polypeptides are produced.